# PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

To:

see form PCT/ISA/220

# PCT

## WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43*bis*.1)

| | |
|---|---|
| Date of mailing *(day/month/year)* see form PCT/ISA/210 (second sheet) | |
| Applicant's or agent's file reference<br>see form PCT/ISA/220 | **FOR FURTHER ACTION**<br>See paragraph 2 below |

| International application No. | International filing date *(day/month/year)* | Priority date *(day/month/year)* |
|---|---|---|
| PCT/IB2004/003804 | 04.11.2004 | 14.11.2003 |

International Patent Classification (IPC) or both national classification and IPC
A61K9/00

Applicant
JAGOTEC AG

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☐ Box No. II Priority
- ☐ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43*bis*.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☐ Box No. VIII Certain observations on the international application

2. **FURTHER ACTION**

If a demand for International preliminary examination is made, this opinion will usually be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA"). However, this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notifed the International Bureau under Rule 66.1*bis*(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of three months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

| Name and mailing address of the ISA: | Authorized Officer |
|---|---|
| European Patent Office - P.B. 5818 Patentlaan 2<br>NL-2280 HV Rijswijk - Pays Bas<br>Tel. +31 70 340 - 2040 Tx: 31 651 epo nl<br>Fax: +31 70 340 - 3016 | Ventura Amat, A<br>Telephone No. +31 70 340-3562 |

# WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/IB2004/003804

## Box No. I Basis of the opinion

1. With regard to the **language**, this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.

   ☐ This opinion has been established on the basis of a translation from the original language into the following language , which is the language of a translation furnished for the purposes of international search (under Rules 12.3 and 23.1(b)).

2. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:

   a. type of material:

   ☐ a sequence listing

   ☐ table(s) related to the sequence listing

   b. format of material:

   ☐ in written format

   ☐ in computer readable form

   c. time of filing/furnishing:

   ☐ contained in the international application as filed.

   ☐ filed together with the international application in computer readable form.

   ☐ furnished subsequently to this Authority for the purposes of search.

3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

4. Additional comments:

**Box No. V Reasoned statement under Rule 43*bis*.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

1. Statement

| | | | |
|---|---|---|---|
| Novelty (N) | Yes: | Claims | |
| | No: | Claims | 1-10 |
| Inventive step (IS) | Yes: | Claims | |
| | No: | Claims | 1-10 |
| Industrial applicability (IA) | Yes: | Claims | 1-10 |
| | No: | Claims | |

2. Citations and explanations

**see separate sheet**

**Re Item V.**

1 The following documents are referred to in this communication:
D1 : WO 01/78693 A (CHIESI FARMACEUTICI) 25 October 2001 (2001-10-25)
D2 : US 6528096 (ROSELLA MUSA ET AL.) 4 March 2003 (2003-03-04)
D3 : WO 00/28979 A (SKYEPHARMA AG) 25 May 2000 (2000-05-25)

2 NOVELTY

The present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of claim 1-10 is not new in the sense of Article 33(2) PCT.

Independent claim 1 describes a dry powder for inhalation comprising drug particles and carrier particles, further containing magnesium stearate particles in an amount of at least 0.5% by weight of the formulation disposed on the surface of the carrier such that the surface coverage of the carrier particles is less than 10%. It is understood that the range of surface coverage is between 0% (no surface coverage) and 10%.

Independent claim 8 describes a method of making a dry powder for inhalation comprising the step of blending magnesium stearate with a carrier material in a diffusion blender for a period of less than 30 minutes.

Document D1 discloses (claims 1,2,4,6,9; page 11, lines 3-8) a powder for dry powder inhalers comprising a mixture of a drug and granules comprising an excipient and 1 to 10% by weight of magnesium stearate where a degree of coating of at least 5% is achieved. This is relevant for claims 1-7 and 10.

Document D2 discloses (claims 15,16; column 3, lines 30-42; column 4, example 1, table 2) a method of making a dry powder for inhalation comprising the step of blending magnesium stearate with a carrier material using a Turbula mixer for a period of at least 2 minutes. This is relevant for claims 8 and 9,

Document D3 discloses (claims 1,4,17, page 8, lines 7-11; page 9, line 16 to page

10, line 6) a dry powder for inhalation comprising magnesium stearate (0.1-2%) but no surface coating of the carrier is mentioned. This is relevant for claims 1,3-7 and 10.

3 INVENTIVE STEP

The documents D1, D2 and D3 appear to be of particular relevance as far as inventive step is concerned (Article 33(3) PCT). These documents solve indeed the same problem, namely, the aggregation of active particles in dry powder inhalers leading to poor bulk properties of the powder such as poor flowability.

Therefore, as no unexpected effect for the present composition (as far as novel) over the prior art compositions has been demonstrated, this composition does apparently not fulfill the requirements of Article 33 (3) of PCT.